K071457 p1/2

Radius Medical Technologies
510(k) Summary of Safety and Effectiveness
May 22, 2007

SEP 25 2007

A. GENERAL INFORMATION

Submitter's Name:	Radius Medical Technologies, Inc.
Address:	15 Craig Road Acton, MA 01720
Contact Person:	Maureen A. Finlayson
Device Generic Name:	Snare
Device Trade Name:	Radius Snare
Classification Name:	Embolectomy Catheter (MMX)

B. INDICATIONS

The Radius Snare is intended for use in the cardiovascular system and hollow viscous to retrieve and/or manipulate objects using minimally invasive surgical procedures. Manipulation procedures include retrieval and/or repositioning of intravascular foreign objects such as coils, balloons, catheters and/or guidewires within the cardiovascular system.

C. DESCRIPTIVE CHARACTERISTICS

The Radius Snare is composed of two primary parts: a stainless steel outer sheath tube and a stainless steel core wire with a loop snare attached to the distal end. The outer sheath acts as a catheter through which the core wire, with snare, slides.

The Radius Snare has loop sizes which range from 5 - 35 millimeters. The over-all length of the device is 150 centimeters.

The Radius Snare is packaged in a mylar/Tyvek pouch and ETO sterilized to SAL 10^{-6}.

D. COMPARATIVE INFORMATION

Substantial equivalence of the modified Radius Snare is based on Design similarities and Performance testing equivalency to the currently marketed Snare (K021441)

The modified Radius Snare and currently marketed Radius Snare (K021441) are substantially equivalent in terms of size, materials of construction, performance characteristics, and basic design. The differences have no effects on the performance or safety of the Radius snare as evaluated in the performance testing.

E. PERFORMANCE TESTING

Performance testing to assess the impact of the modifications was from the FDA guidance document "Coronary and Cerebrovascular Guidewire Guidance" dated January 1995.

CONCLUSION:

Based on the indications for use, technological characteristics, and safety and performance testing, the proposed modifications to the Radius Snare meets the minimum requirements that are considered adequate for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Radius Medical Technologies, Inc.
c/o Ms. Maureen A. Finlayson
President
15 Craig Road
Action, MA 01720

SEP 25 2007

Re: K071457
Radius Snare
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: MMX
Dated: August 27, 2007
Received: August 28, 2007

Dear Ms. Finlayson:

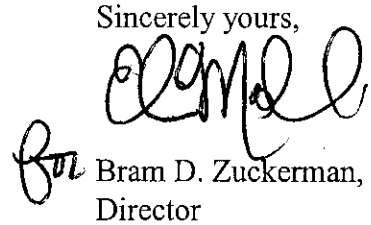
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K071457

Device Name: Radius Snare

Indications For Use:

The Radius Snare is intended for use in the cardiovascular system and hollow viscous to retrieve and/or manipulate objects using minimally invasive surgical procedures. Manipulation procedures include retrieval and/or repositioning of intravascular foreign objects such as coils, balloons, catheters and/or guidewires within the cardiovascular system.

Prescription Use ___X_____ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801.109 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K071457

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